UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION AT CINCINNATI

Levi Pierson and Jackie Pierson,

Plaintiffs, Case No. 1:24-cv-368

v. Judge Michael R. Barrett

Elutia, Inc. f/k/a Aziyo Biologics, Inc.
and Medtronic Sofamor Danek USA, Inc.,

Defendants.

OPINION & ORDER

This matter is before the Court on the partial Motion to Dismiss (Doc. 8) filed by Defendant Elutia, Inc., formerly known as Aziyo Biologics, Inc. ("Aziyo"). Plaintiffs have filed a memorandum in opposition (Doc. 10) and Aziyo has filed a reply (Doc. 12). As discussed below, Aziyo's Motion, seeking dismissal of Plaintiffs' strict liability and warranty claims, will be GRANTED.

I. BACKGROUND

FiberCel Fiber Viable Bone Matrix ("FiberCel") consists of "cancellous bone particles with preserved cells[,] demineralized cortical fiber[,] and other materials" that "contain the scaffold, growth factors[,] and other materials required for regeneration critical for successful bone formation." (Doc. 3, Complaint, ¶ 18). FiberCel is used in "orthopedic and reconstructive bone grafting procedures with the use of autologous bone or other forms of allograft bone or alone as a bone graft." (*Id.* ¶ 20). Put more simply, FiberCel "is used as a bone void filler in various orthopedic and spinal procedures." (Doc. 10, Plaintiffs' Response in Opposition, PAGEID 124).

FiberCel is manufactured by Defendant Aziyo and exclusively distributed in the United States by Defendant Medtronic Sofamor Danek ("Medtronic"). (Doc. 3, Complaint,

¶¶ 7–10, 23). FiberCel is regulated by the U.S. Food & Drug Administration ("FDA"). (*Id.* ¶ 19).

Plaintiff Levi Pierson underwent lumbar spine surgery on April 2, 2021 at Mayfield Clinic (in Cincinnati, Ohio). (*Id.* ¶ 38). The surgery included bone grafting using FiberCel that, unfortunately, was contaminated with *Mycobacterium tuberculosis*. (*Id.* ¶¶ 32, 39, 40). Pierson tested positive for tuberculosis ("TB") following his surgery. (*Id.* ¶¶ 36, 41).[1] As a result of being treated for TB, Pierson "continues to suffer from intermittent back pain, weakness, fatigue, anxiety, and depression" and will "require continued medical monitoring now and into the future[.]" (*Id.* ¶¶ 44–47).

Plaintiffs filed suit in the Hamilton County, Ohio Court of Common Pleas. (*See* Doc. 1-1 PAGEID 7). With Medtronic's consent, Aziyo removed the case here. (*See* Docs. 1, 1-3, 1-5). Pierson and his spouse[2] assert claims against Aziyo (and Medtronic) for negligence (Count I)[3], breach of implied warranty (Count II)[4], breach of express warranty (Count III)[5], gross negligence (Count IV)[6], strict (products) liability for manufacturing defect (Count V)[7] and failure to warn (Count VI)[8], and loss of consortium

[1] On June 2, 2021, the FDA issued an urgent voluntary recall of FiberCel, specifically three products from Donor Lot Number NMDS210011. (*Id.* ¶ 30). Aziyo initiated the recall in response to reports of patients testing positive for TB after either an orthopedic or spinal procedure. (*Id.* ¶ 31). Mayfield had received units from the contaminated donor lot. (*Id.* ¶¶ 34, 35, 39). Pierson was implanted with one of them. (*Id.* ¶ 40).

[2] Plaintiff Levi Pierson and Plaintiff Jackie Pierson are husband and wife. (Doc. 3, Complaint, ¶ 2).

[3] (*See* Doc. 3, Complaint, ¶¶ 50–57).

[4] (*See* Doc. 3, Complaint, ¶¶ 58–65).

[5] (*See* Doc. 3, Complaint, ¶¶ 66–73).

[6] (*See* Doc. 3, Complaint, ¶¶ 74–81).

[7] (*See* Doc. 3, Complaint, ¶¶ 82–94).

[8] (*See* Doc. 3, Complaint, ¶¶ 95–110).

(Count VIII)[9].[10] Aziyo has moved to dismiss Counts II, III, V, and VI.[11]

II. LAW & ANALYSIS

Standard. The Rule 12(b)(6) standard is well-established. To withstand a dismissal motion, a complaint must contain "more than labels and conclusions [or] a formulaic recitation of the elements of a cause of action." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (cleaned up). Courts do not require "heightened fact pleading of specifics, but only enough facts to state a claim for relief that is **plausible** on its face." *Id.* at 570 (bold emphasis added).[12] "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*). A district court examining the sufficiency of a complaint must accept the well-pleaded allegations of the complaint as true. *Id.*; *DiGeronimo Aggregates, LLC v. Zemla*, 763 F.3d 506, 509 (6th Cir. 2014).

Applicable Statute. Ohio's blood and tissue shield statute reads in pertinent part:

> [T]he procuring, furnishing, donating, **processing, distributing, or using** of human whole blood, plasma, blood products, blood derivatives, and products, corneas, **bones,** organs, **or other human tissue** except hair, for the purpose of injecting, transfusing, or **transplanting** the fluid or body part in another human body, **is considered for all purposes as the rendition of a service by every person participating in the act and not a sale** of any such fluid or body part. **No warranties of any kind or description are applicable to the act.**

[9] (*See* Doc. 3, Complaint, ¶¶ 121–126).

[10] Plaintiffs also sue Medtronic for supplier liability (Count VII). (*See* Doc. 3, Complaint, ¶¶ 111–120).

[11] Medtronic answered Plaintiffs' Complaint and filed a crossclaim against Aziyo for common law indemnity. (*See* Doc. 11).

[12] "[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of th[e] facts is improbable, and 'that a recovery is very remote and unlikely.'" *Twombly*, 550 U.S. at 556 (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)).

Ohio Rev. Code § 2108.30 (bold & underline emphasis added).

Plaintiffs' Strict Liability and Warranty Claims Are Not Facially Plausible. Aziyo maintains that Ohio's blood and tissue shield statute bars strict liability and warranty claims related to FiberCel. The Court agrees.

"The concept of strict liability in tort involves a **sale** by a party customarily engaged in selling that product." *Morse v. Riverside Hosp.*, 339 N.E.2d 846, 850–51 (Ohio Ct. App. 6th Dist. 1974) (citations omitted) (bold emphasis added). In *Morse*, a patient developed hepatitis after being transfused with contaminated blood plasma. *Id.* at 848. Her common law claims for negligence could proceed to trial against the blood bank, but, under § 2108.30, her causes of action "based upon a breach of warranty and strict liability in tort" were "untenable." *Id.* at 850–51.[13]

Plaintiffs insist that FiberCel is not covered by the statute. FiberCel is a human tissue *product*, known as an HCT/P[14], that is "highly developed" and "manipulated". (Doc. 10, Plaintiffs' Response in Opposition, PAGEID 128–29 (citing https://elutia.com/wp-content/uploads/2020/07/IFU-0021-Rev03-FiberCel.pdf (last visited 10/11/2024))). It is more than *just* human tissue, but, instead, a "manufactured product" that can include synthetic ingredients. (*Id.*)

Plaintiffs also rely on a textual argument. The statute explicitly applies not only to "blood" but also to "blood derivatives" and "blood products". The statute also explicitly applies to human "tissue". However, the Ohio General Assembly did not concomitantly

[13] *See Zaccone v. Am. Red Cross*, 872 F. Supp. 457, 460 (N.D. Ohio 1994) (recognizing—in a case where a patient was transfused with blood infected with HIV and later died from AIDS—that, "In Ohio, the procuring, processing, distributing, or using of human blood or blood products for the purpose of transfusions is a service.").

[14] *See* Human Cells, Tissues, and Cellular and Tissue-Based Products, 21 C.F.R. § 1271.

include "tissue derivatives" and "tissue products".

Plaintiffs cite no precedent, binding or persuasive, for either theory. And other federal courts have outright rejected them. For example, a district court in West Virginia, applying the Ohio statute (in multidistrict litigation), dismissed strict liability and breach of warranty claims against a defendant that distributed pelvic mesh devices, a different type of processed human tissue. *Hatfield v. Coloplast Corp.* (*In re Coloplast Corp. Pelvic Support Sys. Prods. Liability Litig.*), 219 F. Supp.3d 577 (S.D. W.Va. 2016).[15] Further, a district court in Florida recently acknowledged that Florida's tissue shield statute applied to FiberCel under the same set of facts. *Heitman v. Aziyo Biologics, Inc.,* No. 3:24-cv-61-MCR-ZCB, 2024 WL 4019318, at *2 (N.D. Fla. July 22, 2024). Of note, the Florida statute refers only to human "tissue", with no mention of "derivatives" or "products". *See* Fla. Stat. § 672.316(6).

The contention that FiberCel is processed *so* much that it no longer qualifies as "human tissue" is unpersuasive. Construing a similarly worded statute, a district court in North Carolina reasoned that the legislature included "processing" *and* "using" and did *not* modify "processing". *Sherrill v. Aziyo Biologics, Inc.*, No. 5:21-CV-00172-KDB-SCR, 2024 WL 1985835, at *4 (W.D.N.C. Mar. 29, 2024), *report & recommendation adopted*, 2024 WL 1979452 (W.D.N.C. May 3, 2024).[16] Thus, there is no indication of an intent to

[15] Plaintiffs label *Hatfield* (*In re Coloplast*) as distinguishable, in that "the tissue at issue was a piece of natural human tissue (fascia lata tissue) that was processed and dehydrated so as to retain the exact same structure of the original tissue." (*See* Doc. 10, Plaintiffs' Response in Opposition, PAGEID 132 (citing *Hatfield* (*In re Coloplast*), 219 F. Supp.3d at 578)). But that's not what the court says in its analysis. The Ohio statute applied to the Fascia Lata allograft because there was "no dispute as to whether Coloplast distributed **processed** human tissue[.]" *Id.* at 581 (bold emphasis added). "[P]rocessed" is used as an adjective describing the noun "human tissue"; its meaning is not otherwise limited or restricted.

[16] *See also Lokkart v. Aziyo Biologics, Inc.*, No. 2:23-cv-01961-HDV-E, 2024 WL 3057364, at *4 (C.D. Cal. May 29, 2024) ("FiberCel, a human tissue allograft, falls squarely under the four corners of

cover only "simple" processes as opposed to "complex" ones. *Id.* In addition, as Plaintiffs note, FiberCel is an HCT/P, which is defined as an article "containing or consisting of human cells or tissues that are intended for implantation, . . . into a human recipient." 21 C.F.R. § 1271.3(d). Pertinent here, HCT/Ps are "minimally manipulated", meaning, for "structural" tissue, "processing that does not alter **the original relevant characteristics** of the tissue relating to the tissue's utility for reconstruction, repair, or replacement[,]" and for "cells or nonstructural" tissues, "processing that does not alter **the relevant biological characteristics** of cells or tissues." *Id.* §§ 1271.3(f) (bold emphasis added), 1271.10(a)(1). Given this FDA classification, discovery to uncover "the exact composition" of FiberCel, (*see* Doc. 10, Plaintiffs' Response in Opposition, PAGEID 129, 133–34), would be gratuitous.

Plaintiffs' public policy argument—that Aziyo doesn't deserve the same protection as non-profit blood and tissue banks—also fails. (Doc. 10, Plaintiffs' Response in Opposition, PAGEID 131–32). True, Aziyo is a for-profit commercial entity. But the Ohio statute applies to "**every person** participating" in the "processing" or "using" of "bones" or "other human tissue" for the purpose of "transplanting the . . . body part in another human body[.]" *See Hatfield* (*In re Coloplast*), 219 F. Supp.3d at 581 n.2 ("Human tissue and blood shield statutes have been interpreted to apply to for-profit entities."). Finally, "there is a nationwide antipathy over applying products-liability or strict-liability concepts to body parts such as blood and tissue. Indeed, no court has ever applied strict liability to the distribution of human tissue." *Id.* at 581 (cleaned up).

California's human tissue shield statute."); *Zydek v. Aziyo Biologics, Inc.*, No. 23 C 3016, 2024 WL 197264, *2 (N.D. Ill. Jan. 18, 2024) (same, but under 745 Ill. Comp. Stat. § 40/1).

III. CONCLUSION

For the reasons just discussed, Defendant Aziyo's Motion to Dismiss (Doc. 8) Counts II, III, V, and VI (pursuant to Fed. R. Civ. P. 12(b)(6)) is hereby **GRANTED**.

IT IS SO ORDERED.

/s/ Michael R. Barrett
Michael R. Barrett, Judge
United States District Court